January 29, 2019

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SanBio Announces Topline Results from a Phase 2b Study in the U.S. Evaluating SB623, a Regenerative Cell Medicine for the Treatment of Patients with Chronic Stroke

SanBio Co., Ltd. (hereafter “the Company”) announces today that SanBio and Sumitomo Dainippon Pharma Announce Topline Results from a Phase 2b Study in the U.S. Evaluating SB623, a Regenerative Cell Medicine for the Treatment of Patients with Chronic Stroke as attached.

The impact of this event does not affect the Company’s consolidated operating performance for the fiscal year ending January 31, 2019.

January 29, 2019

SanBio Co., Ltd.
Sumitomo Dainippon Pharma Co., Ltd.

SanBio and Sumitomo Dainippon Pharma Announce Topline Results from a Phase 2b Study in the U.S. Evaluating SB623, a Regenerative Cell Medicine for the Treatment of Patients with Chronic Stroke

SanBio Co., Ltd. (Head Office: Chuo-ku, Tokyo, Japan; President: Keita Mori) and Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura) announced today that a Phase 2b study conducted in the U.S. evaluating SB623, a regenerative cell medicine under development for the treatment of patients with chronic motor deficits due to ischemic stroke, did not meet its primary endpoint.

The study examined the efficacy and safety of SB623 in 163 patients with motor deficits associated with chronic ischemic stroke. The 163 patients were randomized to one of three treatment groups: 2.5 million SB623 cells, 5 million SB623 cells, and a sham surgery (control) group.

The primary endpoint of the study was the proportion of patients whose Fugl-Meyer Motor Scale (FMMS) improved at least 10 points from baseline at six months after treatment. The SB623 treatment groups did not demonstrate a statistically significant improvement compared to the control group, and did not meet its primary endpoint. Additionally, no safety issues were observed for SB623.

The additional analyses of the study results are being conducted. Based on the additional analyses, SanBio and Sumitomo Dainippon Pharma will consider future development plans of SB623. The results of the study will be presented at future scientific congresses and elsewhere.

【About SB623】

SB623 are allogeneic mesenchymal stem cells (MSCs), prepared by processing and cultivating bone marrow stromal cells isolated from healthy donors. SB623 cells are administered in the nerve tissue of the brain where they promote the regeneration of damaged neuronal cells. Unlike autologous cell therapies that require individualized cell preparation at the clinical site, SB623 production can be scaled up from a single donor's cells, enabling delivery of uniform quality products to a large number of stroke patients.

In September 2014, SanBio, Inc. (Head Office: Mountain View, California, US), a US subsidiary of SanBio Co., Ltd., and Sumitomo Dainippon Pharma Co., Ltd. had entered into a joint development and license agreement for exclusive marketing rights in North America for SB623, under development for the treatment of chronic stroke. The study is being conducted jointly by SanBio, Inc. and Sunovion Pharmaceuticals Inc., a US subsidiary of Sumitomo Dainippon Pharma Co., Ltd.

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